

6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-5188

1468 70 457-5

March 22, 2000

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Rexall and Sundown brand names bearing the following statement(s) on the label and/or in the labeling:

<u>Valerian Root, Valerian Root Complex (Rexall)</u>: For restful well-being. Valerian's calming properties have long been known in Europe where it is used to soothe nervousness, tension and restlessness, and enhance serene, restful sleep. Valerian comes from the root of a tall aromatic flowering plant that has been prized since ancient Roman times for its calming and rest-promoting properties.

<u>Valerian Root Complex</u>: [It is] for restful well-being. Valerian's calming properties have long been known in Europe where it is used to soothe tension and restlessness and enhance serene, restful sleep.

<u>Valerian Root (Sundown)</u>: Sundown's Whole Herb Valerian Root contains the natural balance of active plant constituents needed to soothe over-activity, tension and restlessness and support serene, restful sleep. Relax with Sundown's Valerian, nature's natural relaxant. Valerian has been used for centuries to calm upset nerves, soothe tension and support rest. Valerian's calming properties result from its stabilizing effect on the central nervous system.

<u>Valerian Root Complex (Sundown):</u> Relax with Sundown's Valerian, nature's natural relaxant. Valerian has been used for centuries to calm upset nerves and support serene, restful sleep. Valerian's calming properties result from its stabilizing effect on the central nervous system. Sundown's Valerian Root Complex is a relaxing special herbal blend of valerian, kava kava and passionflower that helps enhance serene, restful sleep.

Food and Drug Administration March 22, 2000 Page 2

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs and Assistant General Counsel

Word Shur Inch

Enclosure